OPTN/UNOS Histocompatibility Committee
Report to the Board of Directors
November 12-13, 2014
St. Louis, MO

Dolly Tyan, Ph.D., Chair
Robert Bray, Ph.D., Vice Chair

Contents

OPTN/UNOS Histocompatibility Committee
Report to the Board of Directors
November 12-13, 2014
St. Louis, MO

Dolly Tyan, Ph.D., Chair
Full Name, Vice Chair

This report reflects the work of the OPTN/UNOS Histocompatibility Committee during the June 2014 – November 2014 period.

Action Items

1. **Expanding Candidate and Deceased Donor HLA Typing Requirements to Provide Greater Consistency Across Organ Types**

   Public Comment: *March 14 – June 13, 2014*

   The proposed changes make the HLA typing methods and list of HLA loci to be reported consistent for deceased donors across all organ types. The required methods and list of HLA loci to be reported will apply both when policy requires HLA typing be performed and reported on the deceased donor prior to allocation (i.e. for kidney, kidney-pancreas, and pancreas allocation) and in instances where HLA typing is required only if requested by the candidate's transplant program (i.e. for heart, heart-lung, and lung allocation). The proposal includes new requirements for reporting HLA-DQA and HLA–DPB for deceased donors. The time period for reporting deceased donor HLA typing remains different by organ type to meet varying clinical requirements for timing of transplants. The proposal newly requires HLA typing to be performed and reported for deceased liver donors if requested by a transplant program and makes HLA typing requirements for deceased pancreas islet donors and candidates consistent with those for deceased pancreas donors and candidates. The Committee reviewed and discussed public comment feedback during the August 11, 2014 in person meeting. The Committee unanimously agreed the proposal should be programed to include DQA and DPB fields in DonorNet® and DQA and DPB fields in Waitlist® as unacceptable antigens. To access a detailed summary of the proposal, please reference the briefing paper in **Exhibit A**. The Committee voted 12-Yes, 0-No, 0-Abstentions to recommend the Board of Directors approve the following resolution:

   RESOLVED, that additions and modifications to Policies 2.11.A (Required Information for Deceased Kidney Donors); 2.11.B (Required Information for Deceased Liver Donors); 2.11.C (Required Information for Deceased Heart Donors); 2.11.D (Required Information for Deceased Lung Donors); 2.11.E (Required Information for Deceased Pancreas Donors); 3.4.D (Candidate Human Leukocyte Antigen (HLA Information); and 4.2 (Requirements for Performing and Reporting HLA Typing); as set forth in Exhibit A, are hereby approved effective pending programming and notice to the membership.

Committee Projects

2. **Histocompatibility Bylaws Rewrite: Phase II**

Public Comment: *September 29 – December 5, 2014*
Board Consideration: *June 2015 (Estimated)*

Many of the Bylaws governing laboratories are ambiguous, fail to reflect advances in technology and current clinical practice, or are more appropriately monitored by the histocompatibility accrediting agencies (ASHI and CAP). As a result, the Committee conducted a comprehensive review of the Bylaws governing histocompatibility laboratories. The Committee determined that rewriting the Bylaws was a large project and decided to split the rewrite into two phases. In November 2013, the Committee completed and the Board of Directors approved the first phase of changes in the Bylaws. This phase included changes that required all laboratories to comply with the requirements in the documents issued by ASHI and CAP (as of a date certain), expanded the definition of changes in key personnel, and required laboratories to submit a coverage plan to the OPTN. Those changes became effective February 1, 2014. The Committee is now proposing the following additional changes:

- Adding the general supervisor to the list of laboratory key personnel.
- Creating two pathways for approval of histocompatibility laboratory directors--M.D./D.O. or earned doctoral degree. Each pathway specifies particular education, experience, and certification requirements. The Committee also proposes the addition of a foreign equivalent qualifier for both pathways (current Bylaws are silent on foreign equivalent education and experience for laboratory directors).
- Simplifying requirements for the technical supervisor, general supervisor, and clinical consultant by only requiring that these individuals meet the requirements in the federal Clinical Laboratory Improvement Amendments (CLIA).
- Eliminating references to the histocompatibility technologist, since no requirements for this position are included in the Bylaws.
- Adding criteria for performance review of a histocompatibility laboratory, including HLA typing errors that result in an incompatible transplant or the reallocation of an organ.
- Removing sections that are out of date or more appropriately monitored by the histocompatibility accrediting agencies.

In early June 2014, the Committee reviewed recommendations from the Bylaws Rewrite Subcommittee and endorsed a draft for ASHI to evaluate. A conference call was scheduled with ASHI's Board of Directors in mid-June to discuss their evaluation of the proposal. UNOS staff communicated ASHI's comments to the Committee for any necessary changes to the Bylaws and in anticipation of a final vote to release the proposal for fall public comment. In June 2014, the Committee met to review feedback from the histocompatibility accrediting agencies. After discussing feedback, the Committee unanimously agreed to distribute this proposal for public comment. This proposal is currently out for public comment.

3. Addressing HLA Typing Errors

Public Comment: August 2015 (Estimated)
Board Consideration: December 2015 (Estimated)

As part of the histocompatibility comprehensive policy rewrite that was approved in June 2014, the Committee considered policy changes to address HLA typing errors that are reviewed by the Discrepant HLA Typing Subcommittee, but decided to delay sending those changes to the Board of Directors. The Committee discussed preventative and disciplinary solutions for HLA typing errors at its August 2014 in person meeting. The Committee addressed the disciplinary aspect by including in the Bylaws Rewrite Phase II proposal a provision for MPSC review of a laboratory. The MPSC may review a laboratory if one or more HLA typing errors or reporting errors on a donor results in an incompatible transplant or the re-allocation of an organ to someone other than the intended recipient.

After development of the disciplinary aspect, the Committee thought it necessary to discuss solutions to prevent HLA typing errors from occurring prior to allocation or to detect them prior to transplant. Leadership explained two possible solutions to prevent HLA typing errors:

- Require second person confirmation for reporting HLA
- Require recipient laboratories to re-type deceased donors

The Committee determined that uncertainty exists with respect to the magnitude of HLA typing errors on organ allocation, and explored limitations of the current data on HLA typing errors.

The Committee believes the extent of problem is not yet known and tasked the Discrepant HLA Typing Subcommittee with gathering data to fully understand the scope of the problem. The Committee also directed the Discrepant HLA Typing Subcommittee to refocus this project to work on updates to the programming and reports used for the review. The Discrepant HLA Typing Subcommittee will meet to discuss the Committee's requests and recommendations.

4. CPRA and Priority for Kidney Candidates Undergoing Desensitization

Public Comment: January 2016 (Estimated)
Board Consideration: June 2016 (Estimated)

The Committee continues to discuss CPRA prioritization points for kidney candidates undergoing desensitization. Under the kidney allocation system, highly sensitized kidney candidates who undergo desensitization lose allocation points associated with their CPRA score, reducing their opportunity for kidney offers. Previously, a workgroup comprised of members of the Histocompatibility, Kidney Transplantation, and Minority Affairs Committees held an introductory call on this project and discussed barriers to getting data on how many patients would benefit from a policy change.

The workgroup decided that the most effective step for moving forward is to conduct a survey of kidney transplant programs to learn whether more programs would utilize

desensitization for highly sensitized candidates if these candidates could keep the prioritization associated with their CPRA score for a period of time.

At the Committee's August 11-12, 2014, in-person meeting, an update on the survey's design was presented to the Committee. A series of draft survey questions were presented and reviewed by the Committee. The Committee recommended the KAS Desensitization Workgroup refine the survey questions for eventual distribution.

5. <u>Evaluating Priority Points for DR Matching in Deceased Kidney Allocation</u>

Public Comment: August 2016
Board Consideration: December 2016

In fall 2013, the DR Mismatch Subcommittee met to review data aimed at addressing two issues:

- To assess the impact of lower level of HLA-DR mismatch on kidney graft survival;
- To test the hypothesis that lower levels of HLA-DR and –DQB mismatch is superior to lower DR mismatch alone with a secondary goal of assessing whether HLA-DQB matching should be considered as an additional element in organ allocation

During the Committee's August 11-12, 2014 meeting, a summary of results and conclusions drawn from the data were presented. The Committee agreed with the subcommittee's conclusion that based on data shown to date, there is no added value to adding priority points for DQB matching in addition to those already assigned for HLA-DR matching in kidney allocation. The Committee members also agreed the DR Matching Subcommittee should focus on whether the current priority for lower levels of DR mismatch is appropriate or whether additional priority should be given to those patients.

The Committee directed the DR Matching Subcommittee to request at their next meeting multivariable analysis to determine if lower DR mismatch levels are associated with better deceased donor kidney graft survival after adjusting for other facts that affect survival (different donor, recipient and transplant characteristics including CPRA value, induction, cold ischemia time). The DR Matching Subcommittee will specify several factors to be included in the model and will consult SRTR in suggesting additional variables.

The Committee discussed a request for simulation modeling to analyze the outcome if an increased number of points was given for a lower level of DR mismatch during deceased donor kidney allocation. The Committee ultimately decided to wait until they review the results of multivariable analysis and then revisit this request. The Committee is aware that they will need to involve the Kidney Committee prior to requesting simulation modeling.

6. Histocompatibility Guidance Document

Public Comment: *N/A*
Board Consideration: *June 2015*

In June 2014, the Board of Directors approved the histocompatibility comprehensive policy rewrite proposal. As part of this rewrite, the Board of Directors voted to move numerous sections of policy to a guidance document. Although these sections do not contain member requirements, the Committee determined they are nonetheless useful to members.

The Committee decided to create a subcommittee to develop the proposal for the Committee's review. AST and ASTS made a formal request to view the guidance document before it is forwarded to the Board of Directors.

7. CPRA Manuscript

Public Comment: *N/A*
Board Consideration: *N/A*

The goal of this manuscript is to describe the changes in CPRA distribution that have occurred since the CPRA replaced PRA for kidney allocation based on analysis performed for the Committee. This manuscript is the final step in CPRA monitoring done by the Histocompatibility Committee. The POC specified this project has a deadline at the end of 2014. The lead member on this project described the structure of the manuscript and will distribute a draft for revisions and circulation before a final submission.

8. Programming Allele Level Typing in UNet^{SM}

Public Comment: *August 2016*
Board Consideration: *December 2016*

Current histocompatibility testing allows for the identification of allele level types of HLA and unacceptable antigens. These allele level types are a more exact indication of a patient's HLA and antibody level. However, there is no structure in UNet^{SM} for laboratories to enter allele level typing. Instead, the laboratory staff must convert the allele level type into one of the existing antigens listed. This increases the likelihood for mistakes, especially since conversion of an allele level type to an antigen is not possible for all alleles. In addition, the inability to list allele level antibodies disadvantages candidates in the screening process because, when only antigens can be entered, candidates are screened from donors from whom they could safely accept an organ.

Compared to the other projects requested from this Committee, this project is on the lower end of the Committee's prioritization list. This project will require a re-evaluation after current projects advance through the policy process. Members indicated interest in programming the most common alleles before programming all of the alleles.

Committee Projects Pending Implementation

9. Require HLA-C and HLA DQB for Deceased Kidney, Kidney Pancreas, and Pancreas Donors

Public Comment: *March 19, 2010 – July 16, 2010*
Board Approval: *November 2010*
Project Implementation: *First Quarter 2015*

This proposal requires that OPOs and their associated laboratories perform HLA typing of all deceased donors by DNA methods and identify the HLA-A, -B, -Bw4, Bw6, -C, -DR, -DR51, -DR52, -DR53, and –DQ antigens before making any kidney, kidney-pancreas, pancreas, or pancreas isle offers.

10. Update to the HLA Equivalency Tables

Public Comment: *March 3, 2013 – June 6, 2013*
Board Approval: *November 2013*
Project Implementation: *First Quarter 2015*

Current Policy requires the Histocompatibility Committee to recommend updates, on an annual basis, to the HLA Equivalency tables. This project will implement the following changes to the HLA Equivalency tables:

- 8 broad antigens will be eliminated in the Matching Antigen Equivalences tables.
- 4 equivalences will be added and 57 deleted in the Unacceptable Antigen Equivalences tables.
- The Cw13 antigen will be removed from the system completely.

11. Comprehensive Histocompatibility Policy Rewrite

Public Comment: *September 6, 2013 – December 6, 2013*
Board Approval: *June 2014*
Project Implementation: *January 2015*

This proposal reflects recommendations from the Committee following a comprehensive review of the policies governing histocompatibility testing. The Committee proposed several changes in order to align OPTN testing requirements with those in federal regulations. Some changes were in response to requests from UNOS staff to resolve issues with policies identified as difficult to monitor. Finally, the Committee proposed to eliminate numerous sections of the current policies because they are outdated or adequately addressed in the standards required by histocompatibility accrediting agencies (ASHI and CAP).

This proposal became effective September 1, 2014, with the exception of the new deadline for HLA typing discrepancies, which will become effective pending programming and notice to the membership.

Implemented Committee Projects

12. Monitoring Changes of CPRA Calculation

Public Comment: *September 16, 2011 – January 12, 2012*
Board Approval: *June 2012*

Changes to CPRA calculation were implemented on December 5, 2013. Those changes included updating HLA and ethnic frequencies used to calculate CPRA for kidney, kidney-pancreas, and pancreas registrations on the waiting list and adding HLA-C into calculation. On March 20, 2014, the question of whether a candidate was "Tested for anti HLA antibodies" was added to the waiting list to better interpret 0% CPRA value. The committee members reviewed changes in CPRA values immediately after December 2013 implementation and asked to revisit these changes, once more time has passed after implementation.

During the August 11-12 meeting in Chicago, the Committee discussed continuing monitoring of implemented changes and had several data questions. The goal of the request is to monitor the update of HLA and ethnic frequencies used to calculate CPRA with the addition of HLA-C into the calculation and "Tested for anti HLA antibodies" question on the waiting list.

Review of Public Comment Proposals

The Committee reviewed 2 of the 17 policy proposals released for public comment from March – June 2014.

13. Kidney Paired Donation (KPD) Histocompatibility Guidelines to Policy

The Kidney Transplantation Committee's Kidney Paired Donation (KPD) Histocompatibility Testing Policies proposal and public comments were presented to the Histocompatibility Committee for feedback. The Histocompatibility Committee offered the following feedback:

Crossmatching

The Committee recommended requiring a review between the physician/surgeon and the HLA laboratory director (to discuss sensitization history, the possible need for additional screening or crossmatch) if the transplant does not occur within 60 days of the original physical crossmatch.

Frequency of Antibody Screenings

In response to the specific request for feedback regarding the requirement to perform antibody screenings on all candidates every 90 days, the members of the committee were somewhat split in opinion. Half of the committee indicated support for leaving the requirement as is. This half of the committee did not agree that there should be a longer timeframe for candidates who are/were unsensitized on previous screenings, because a longer timeframe (180 days was used, for example) could mean that they would proceed to transplant on what they considered to be very old test results (100 days or more).

The other half thought that it would be more productive to require the collection of sera every 30 days (monthly) instead of specifying the frequency for antibody screenings.

This half of the committee said that having a recent sample to perform the tests is key to this process and that the frequency of screenings should be left as a member specific practice.

Other members of the Committee did not agree that this should be left to the hospital to decide as a protocol, reasoning that many programs are involved in the same match run and they are just as dependent on the outcome as other hospitals, so consistency is key for KPD.

Inactivation Due to Unacceptable Positive Crossmatch

The Committee did not specify a particular opinion as to whether UNOS or the transplant program should be responsible for inactivating the candidate. They did, however, express the hope that the review/reporting turnaround time would be quick so that the candidate is not disadvantaged by not being eligible for match runs for significant periods of time. There will be many instances where the crossmatch is unacceptable because of low level antibodies and the unacceptable antigens are not going to change with the review between the surgeon/physician and the HLA laboratory director.

Members of the Committee suggested that the Kidney Committee consider an additional requirement in these instances – that the program pre-refuse that particular donor for the candidate for subsequent match runs.

14. Modification of the Heart Allocation System

UNOS staff presented a report provided to the Heart Subcommittee of the Thoracic Committee in March of 2014 that described unacceptable antigen reporting on the waiting list for heart candidates and recipients. The Heart Subcommittee has discussed possible modifications to adult donor heart allocation, with the primary focus being on revisions to the prioritization tiers. The Heart Subcommittee identified sensitization as a critical issue for inclusion in a new allocation system, but is still discussing the best mechanism for incorporation into the new system. The Heart Subcommittee was interested in available information on reporting of unacceptable antigens for heart candidates on the waiting list and if that information could be used to identify patients who are sensitized for incorporation into an allocation system. These data were presented to the Histocompatibility Committee for recommendations on the definition of sensitization and how to prioritize patients that are defined as sensitized.

The Histocompatibility Committee recommended the Heart Subcommittee review the existing data, identify the transplant hospitals that reported unacceptable antigens, and determine how many patients they have in their transplant hospital. Afterwards, the Heart Subcommittee can analyze the distribution for the frequency of the sensitization or listing.

The Histocompatibility Committee was also asked to define highly sensitized heart candidates. The Committee responded that kidneys now have an approved sliding scale based on CPRA values and the Thoracic Committee may consider whether a sliding scale can be incorporated into the modeling for hearts so there is recognition that the patient is sensitized but at a higher value of sensitization, patients are given incrementally higher priority.

Meeting Summaries
The Committee held meetings on the following dates:

- June 3, 2014
- June 26, 2014
- August 11, 2014
- August 12, 2014

Meetings summaries for this Committee are available on the OPTN website at:
http://optn.transplant.hrsa.gov/converge/members/committeesDetail.asp?ID=7.

BRIEFING PAPER **OPTN/UNOS**

Expanding Candidate and Deceased Donor HLA Typing Requirements to Provide Greater Consistency Across Organ Types

Table of Contents

BRIEFING PAPER **OPTN/UNOS**

Expanding Candidate and Deceased Donor HLA Typing Requirements to Provide Greater Consistency Across Organ Types

Sponsoring Committee: Histocompatibility Committee

Summary and Goals of the Proposal:

The proposed changes make the HLA typing methods and list of HLA loci to be reported consistent for deceased donors across all organ types. The required methods and list of HLA loci to be reported will apply both when OPTN policy requires HLA typing be performed and reported on the deceased donor prior to allocation (i.e. for kidney, kidney-pancreas, and pancreas allocation) and in instances where HLA typing is required only if requested by the candidate's transplant program (i.e. for heart, heart-lung, and lung allocation). The proposal includes new requirements for reporting HLA-DQA and HLA–DPB for deceased donors. As proposed, HLA-DQA and HLA-DPB will be programmed into DonorNet® for physicians to use in making donor acceptance decisions and in Waitlist as unacceptable antigens to automatically avoid those donors if these unacceptable antigens are listed. The time period for reporting deceased donor HLA typing remains different by organ type to meet varying clinical requirements for timing of transplants. The proposal newly requires HLA typing to be performed and reported for deceased liver donors if requested by a transplant program and makes HLA typing requirements for deceased pancreas islet donors and candidates consistent with those for deceased pancreas donors and candidates.

The goal of this proposal is to improve virtual crossmatching and prevent unexpected positive crossmatches that result in discards or increased cold ischemia time. The proposal is also intended to promote transplant safety by requiring additional information on deceased donors to be used in determining donor and recipient compatibility and post-transplant monitoring.

Background and Significance of the Proposal:

In 2012, the Histocompatibility Committee began conducting a comprehensive rewrite of the OPTN policies governing histocompatibility testing. As part of this effort, the Committee organized all the HLA typing requirements into two tables, one for deceased donors and one for candidates (see below).

Table 1 HLA Typing Requirements for Deceased Donors

Organ	A	B	Bw4	Bw6	C	DR	DR51	DR52	DR53	DPB	DQB
Kidney	●	●	●	●	●	●	●	●	●		●
Pancreas	●	●	●	●	●	●	●	●	●		●
Kidney-Pancreas	●	●	●	●	●	●	●	●	●		●
Heart*	●	●	●	●	●	●				●	●
Lung*	●	●	●	●	●	●				●	●

*For deceased heart and lung donors, if a transplant hospital requires donor HLA typing prior to submitting a final organ acceptance, it must communicate this request to the OPO and the OPO must provide the HLA information required in the table above and document this request. The transplant hospital may request HLA-DPB typing, but the OPO need only provide it if its affiliated laboratory performs this testing.

Table 2: HLA Typing Requirements for Candidates

Organ	A	B	Bw4	Bw6	DR
Kidney alone	●	●	●	●	●
Pancreas alone	●	●	●	●	●
Kidney-Pancreas	●	●	●	●	●

The Committee identified several problems with the current HLA typing requirements:

- It is critical for all transplant physicians to have complete HLA information when making decisions about donor acceptance and performing post-transplant monitoring. However, there are several inconsistencies in the list of HLA types required to be reported for deceased donors across organ types.
- Recent research suggests that antibodies to HLA-DQA and HLA-DPB are frequently observed in sensitized transplant candidates[1]. If donors with the relevant types are not avoided, these antibodies can contribute to adverse graft outcomes. However, these HLA types are not required to be reported on deceased donors. HLA-DPB is currently only required if requested for heart or lung offers and the OPO's laboratory performs this testing. Even if an OPO's histocompatibility laboratory types the donor for HLA-DQA or HLA-DPB prior to allocation, the only way to currently communicate this information is through an attachment function in DonorNet®, which can sometimes be overlooked.

[1] Tambur, AR, JR Leventhal, and JR Zitzner, et al. "Improving organ allocation equity using HLA-DQ information." *Transplantation*. no. 4 (2013): 635-640.

- Publications implicate anti-HLA antibodies may contribute to negative outcomes in pancreas islet transplants and negatively impact the ability of islet recipients to undergo further islet, pancreas, or kidney transplantation.[2] HLA typing could be crucial for evaluating risk from pre-transplant and *de novo* HLA antibodies. However, there are currently no HLA typing requirements for deceased pancreas islet donors or candidates.
- It is critical for heart and lung transplant programs to have deceased donor HLA typing information prior to transplant. However, HLA typing is only required on deceased heart, heart-lung, and lung donors if requested by the candidate's transplant program.
- There is increasing evidence of antibody mediated rejection (AMR) in liver transplantation[3][4]. However, there is currently no requirement for HLA typing to be performed on a deceased liver donor if the candidate's transplant program requests it.
- Deceased donor HLA typing performed using molecular methods provides much superior accuracy and advantages for transplant candidates. However, laboratories are currently required to perform molecular typing on deceased kidney, kidney-pancreas, and pancreas donors only.

Early in the process, the Committee identified a list of solutions to address these problems:

- Make consistent the list of HLA loci required to be reported across organ type.
- Add HLA-DQA and HLA-DPB to the list of HLA loci required to be reported for deceased donors.
- Align requirements for deceased pancreas islet donors and candidates with those of deceased pancreas donors and candidates.
- Require HLA typing be performed and reported for deceased thoracic donors (not merely if requested), either pre-transplant or within a certain period of time after transplant.
- Require HLA typing to be performed for deceased liver donors if requested by the candidate's transplant program.
- Require molecular typing to be performed on all deceased donors (both when OPTN policy requires the typing to be performed and when it is required only if requested by a candidate's physician).

The Committee then presented these solutions to the following groups for feedback:

- Kidney Transplantation Committee
- Liver and Intestine Transplantation Committee
- Organ Procurement Organization (OPO) Committee
- Pancreas Transplantation Committee
- Thoracic Transplantation Committee
- American Society of Histocompatibility and Immunogenetics (ASHI) Board of Directors
- College of American Pathologists (CAP) Histocompatibility Committee and Staff

[2] Campbell, PM, PA Senior, and A Salam, et al. "High Risk of Sensitization After Failed Islet Transplantation." *American Journal of Transplantation* . no. 7 (2007): 2311-2317.

[3] Kozlowski, T, T Rubinas, V Nickeleit, et al. "Liver Allograft Antibody-Mediated Rejection With Demonstration of Sinusoidal C4d Staining and Circulating Donor-Specific Antibodies." *Liver Transplantation*. no.17 (2011): 357-368.

[4] Musat, AI, RM Agni, PY Wai, et al. "The Significance of Donor-Specific HLA Antibodies in Rejection and Ductopenia Development in ABO Compatible Liver Transplantation." *American Journal of Transplantation*. no. 11 (2011): 500-510.

In addition to the list of solutions, the Committee presented data showing that an increasing number of laboratories are reporting HLA-DPB typing results on the Donor Histocompatibility Form (DHF) completed post-transplant. For more information, please see the Supporting Evidence and/or Modeling section.

The OPO Committee expressed general support for the proposal and members indicated that there are more benefits than negatives, especially if the changes decrease unexpected positive crossmatches for kidney allocation. Some members questioned whether requiring new methods and additional loci will add to the overall allocation expense for some OPOs. The Histocompatibility Committee leadership acknowledged that there may be additional cost associated with some of the solutions, but pointed out that the changes may also offset costs OPOs are currently incurring due to unexpected positive crossmatches, increased cold ischemia time, and discards. Several members requested that the Committee consider delayed implementation of any future policy proposal if there is a determination that some laboratories do not have the resources to perform typing for HLA-DQA and HLA-DPB. The Committee leadership responded that Committee will discuss whether or not a delayed implementation will be necessary. The OPO Committee members also cautioned the Committee against any new HLA typing requirements for allocation of thoracic organs that would delay the OPO in making offers.

The Thoracic Transplantation Committee had similar comments with regard to thoracic allocation and any new requirements for HLA typing to be reported prior to match runs (not merely if requested). The Histocompatibility Committee leadership presented OPTN data showing that deceased donor HLA information is now being reported prior to match runs for thoracic organs about 80% of the time (for more information, see the Supporting Evidence and/or Modeling section). Members of the Thoracic Committee expressed the view that it is important to allow the heart and lung allocation process to continue without delay if the potential recipient's physician does not request HLA information on the donor. The Committee did, however, support the notion that molecular typing and the list of types required to be reported should be consistent when HLA information is requested by the candidate's transplant program. After receiving this feedback, the Committee decided not to propose requiring HLA typing for all deceased thoracic donors, but to require molecular typing be performed and the full list of HLA loci to be reported if requested by the candidate's transplant program prior to final acceptance.

The Kidney Transplantation Committee indicated strong support for these proposed solutions, especially with regard to adding HLA-DQA and HLA-DPB to the list of types required to report prior to kidney allocation. Several members of the Committee expressed concern that a number of unexpected positive crossmatches are due to these types not being reported on the match run, and that this problem will only be more complex with implementation of the new kidney allocation system. The Pancreas Transplantation Committee also supported the solutions outlined for additional information to be reported for pancreas donors and candidates and pancreas islet donors and candidates.

Members of the Liver and Intestine Transplantation Committee agreed with the notion that HLA typing should be required if requested by the liver transplant program and that laboratories should be required to report molecular typing results for the complete list of types for the liver transplant physician to consider. In addition, several members commented that the timing specifications for reporting HLA typing for liver allocation or transplantation will vary greatly from that for other organ types. Members requested that the Committee require only that the information be reported in the time period specified by the transplant program.

Both ASHI and CAP indicated support for the proposed solutions.

In December 2013, the Committee held a conference call to review feedback from the OPO and organ specific committees. After discussing the feedback, the Committee unanimously agreed to distribute this proposal for public comment.

Supporting Evidence and/or Modeling:

In the deliberation process, the committee considered or presented the following data:

Molecular typing

Since molecular typing is only currently required for deceased kidney, kidney-pancreas, and pancreas donors, the Committee requested data to determine whether it is common for laboratories to perform HLA typing using other methods for deceased liver or thoracic alone donors. The Committee reviewed data on the typing methods for kidney and/or pancreas donors and donors who donated neither kidney nor pancreas by organ for deceased donors recovered from June 1, 2013 through May 31, 2013 (**Exhibit A**). The results showed:

- Most deceased donors (91.1%) were kidney and/or pancreas donors. The majority (82%) of donors who donated neither kidney nor pancreas were liver alone donors.
- 98.2% of all deceased donors were HLA typed.
- Of the deceased donors that were HLA typed, 99.9% were typed using molecular methods and 17.5% were also typed by serology
- Serological only typing was reported by 3 donor laboratories for 4 donors (0.1% of HLA typed donors). Two of those laboratories reported using molecular methods or both serology and molecular typing for other deceased donors. One laboratory had only one deceased donor and reported typing by serology only. That laboratory reported molecular typing for most kidney, kidney-pancreas and pancreas recipients.

HLA typing for thoracic donors

UNOS staff provided the following data to the OPTN/UNOS Thoracic and OPO Committees on the frequency of HLA typing for deceased thoracic donors and how often HLA was reported for deceased thoracic donors prior to a match run.

While almost all thoracic donors were HLA typed, HLA typing was available prior to 79% of thoracic offers (Table 3).

Table 3. HLA available* prior to match run: thoracic matches run for deceased donors recovered June 1, 2011 – May 31, 2013

Offer type	HLA prior to match run				All	
	No		Yes			
	N	%	N	%	N	%
Heart-lung	980	20.9	3,707	**79.1**	4,687	100.0
Heart	601	19.3	2,519	**80.7**	3,120	100.0
Lung	1,672	22.7	5,708	**77.3**	7,380	100.0
All	3,253	21.4	11,934	**78.6**	15,187	100.0

*at least one antigen reported at the HLA-A, B, and DR loci.

Requiring HLA-DQA and HLA-DPB to be reported for all deceased donors

In order to determine whether to require HLA-DQA and HLA-DPB to be reported for deceased donors, the Committee requested data that would determine the frequency with which solid organ candidates have antibodies to these types. Although the absence of current OPTN data fields and varied clinical practice make it difficult to assess the total number of transplant candidates who would currently have unacceptable antigens listed to these types, the Committee conducted an initial survey among several of the committee members whose laboratories serve transplant programs that screen for antibodies to these HLA types. The Committee requested information on the number of candidates at the program who have unacceptable antigens to HLA-DQA or HLA-DPB according to their program's practice in assigning unacceptable antigens. The results were as follows:

For Lab 1: Out of 2,783 candidates, 21.6% (602 patients) have antibodies to HLA-DQA and 33.7% (939 patients) have antibodies to HLA-DPB.

For Lab 2: Out of 846 candidates, 4.0% (34 patients) have antibodies to HLA-DQA and 4.6% (39 patients) have antibodies to HLA-DPB.

For Lab 3: Out of 2,625 candidates, 1.6% (42 patients) have antibodies to HLA-DQA and 6.6% (173 patients) have antibodies to HLA-DPB.

Please note that the three labs above serve programs with different MFI cutoffs for assigning unacceptable antigens.

Data from Kidney Paired Donation (KPD) programs also showed that HLA-DQA and HLA-DPB antibodies are frequently observed in highly sensitized patients. The percent of candidates with unacceptable HLA-DQA and HLA-DPB antigens increases with higher CPRA values (Figures 1 and 2).

Figure 1. Percentage of OPTN KPD Candidates with HLA-DQA and HLA-DPB unacceptable antigens on June 6, 2014

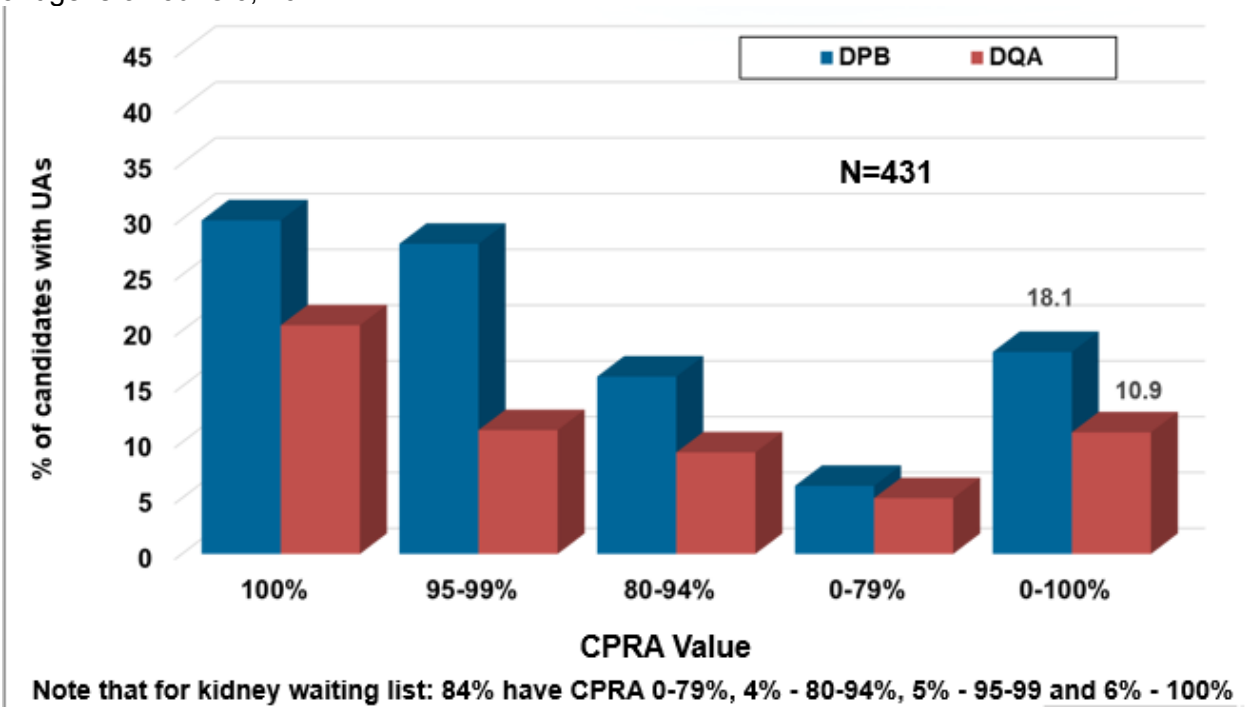
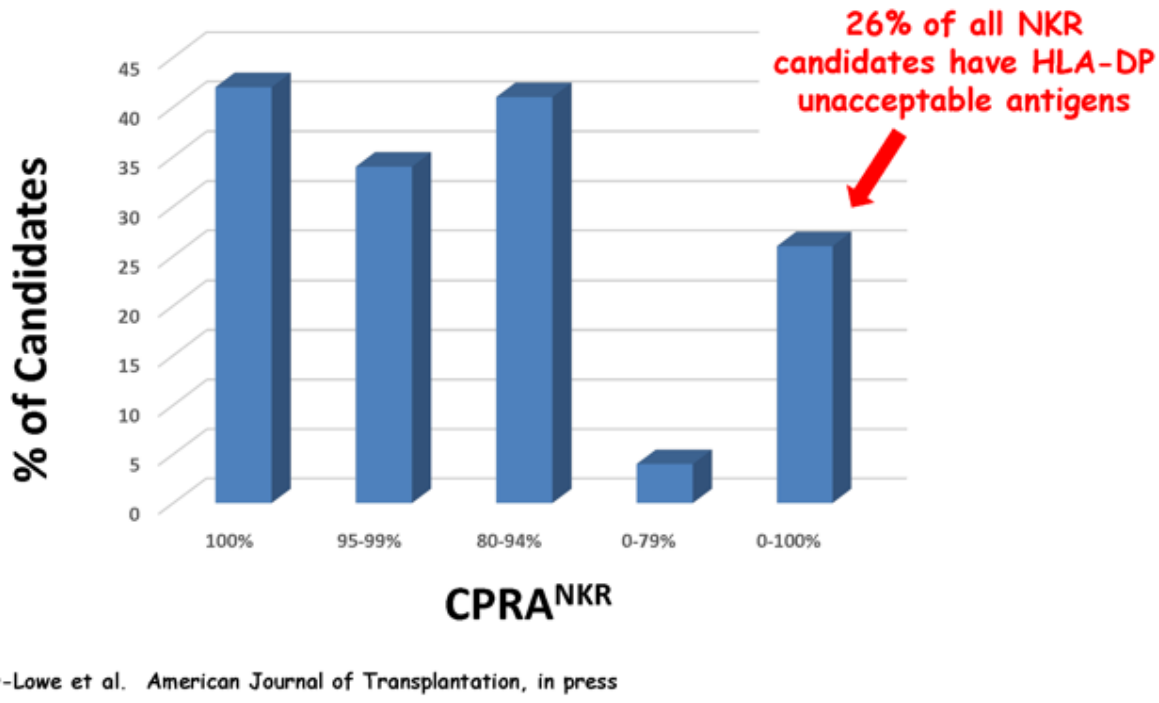


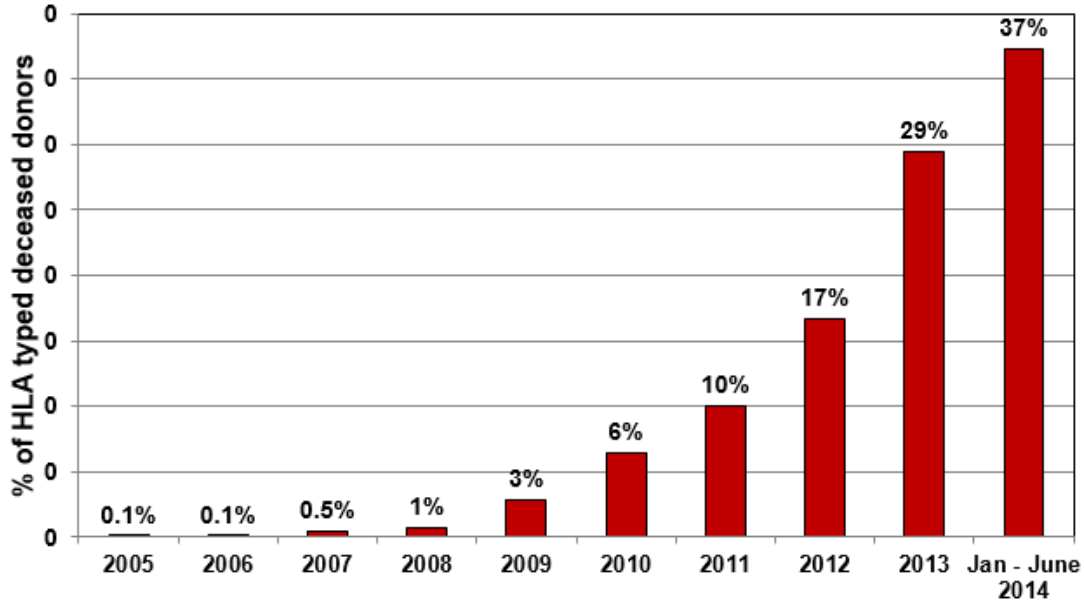
Figure 2. Percentage of NKR Candidates with HLA-DPB Unacceptable Antigens



While neither DQA nor DPB are collected for deceased donors prior to transplant, HLA-DPB is collected on the OPTN donor and recipient histocompatibility forms submitted after transplant. Trends in HLA-DPB typing of deceased donors can be used as a surrogate marker for donation service areas with centers that are considering candidate antibodies to HLA-DPB. As Figure 3

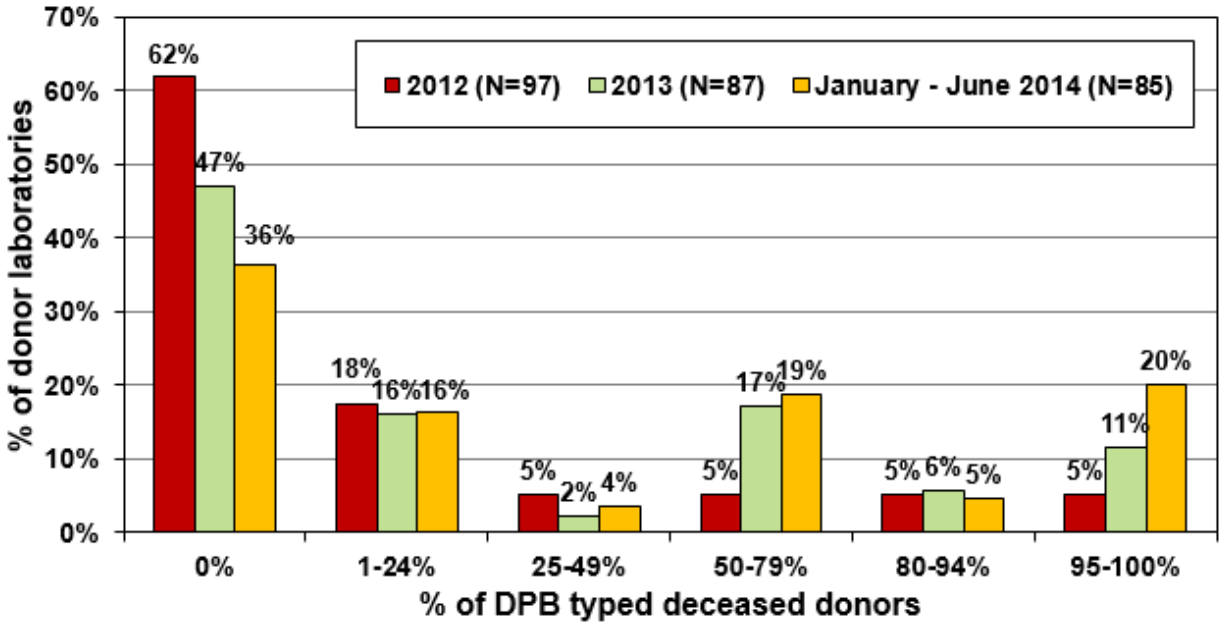
below shows, data suggest that typing for HLA-DPB on deceased donors continues to increase since 2005.

Figure 3. Reporting of HLA-DPB for Deceased Donors on Donor Histocompatibility Forms by Year



The percentage of donation service areas with at least some DPB typed deceased donors increased from 55% in 2012 to 66% and 69% in 2013 and January – June 2014, respectively. During the same time, the percentage of donor laboratories that reported DPB typed deceased donors increased from 38% to 53% and 64%. (Figure 4). In the first six months of 2014, 20% of laboratories reported DPB typing for 95-100% of deceased donors typed by those laboratories.

Figure 4. Distribution of Donor Laboratories by the Percentage of DPB Typed Deceased Donors and Year



For deceased donors not DPB typed by donor laboratories, recipient laboratories subsequently DPB typed deceased donors for some recipients (10% in 2013 vs. 6% in 2012), likely due to candidate's antibodies.

The values on the HLA-DPB dropdown are incomplete and the updated dropdown is currently pending implementation. Due to the incomplete values, some deceased donors typed for HLA-DPB are likely being reported as 'not typed' and the numbers above are likely an underestimate.

HLA typing for pancreas islet candidates
Of the 198 pancreas islet registrations waiting on January 3, 2014, 52% had HLA-A, -B, -Bw4, -Bw6 and –DR reported, 38% had some but not all of these antigens reported, and 10% had no antigens reported.

Expected Impact on Living Donors or Living Donation:

Not applicable; these requirements would only apply to deceased donors and candidates.

Expected Impact on Specific Patient Populations:

This proposal will increase transplant safety for sensitized patients by providing transplant programs with information vital to the donor screening and acceptance process.

Expected Impact on OPTN Key Goals and Adherence to OPTN Final Rule:

This proposal is intended to further objectives in the Final Rule pertaining to efficient management of organ placement by improving virtual crossmatching and, therefore, preventing some unexpected positive crossmatches that result in discards or increased cold ischemia time. It is also intended to further the OPTN strategic goal of promoting transplant safety by preventing negative graft outcomes through more effective donor screening.

Plan for Evaluating the Proposal:

The Histocompatibility Committee will evaluate the effect of this proposal 1 and 2 years post-implementation.

Following implementation, the Committee's hypothesis is that collection of additional data will result in improved allocation due to more accurate virtual crossmatching and that organ offer refusals due to an unacceptable positive crossmatch will decrease. Since external factors and other changes in transplant policy can have an influence on the post-implementation period, interpreting the apparent impact of the additional optional fields based on "before vs. after" analysis must be done with caution.

The following questions, and any others subsequently requested by the Committee, will guide the evaluation of the proposal after implementation:

1. Has the number and the percentage of organ offers refused due to a positive crossmatch decreased?
2. Has the number and percentage of organ offers accepted but organs not transplanted into the intended recipient decreased?

The following performance metrics, and any others subsequently requested by the Committee, will be compared against the data before and after implementation to evaluate the proposal:

1. The number and percentage of offers refused due to a positive crossmatch by organ for kidney, kidney-pancreas and pancreas offers.
2. The number and percentage of offers accepted but organs not transplanted into the intended recipient by organ for kidney, kidney-pancreas and pancreas offers.

The committee will also evaluate the effect of the policy on specific patient populations (pediatric, minority and sensitized candidates).

Additional Data Collection:

This proposal does require additional data collection. If approved, fields for HLA-DQA and HLA-DPB will be required to be reported on all deceased donors prior to match runs for kidney, kidney-pancreas, and pancreas allocation. HLA-A, HLA-B, HLA-Bw4, HLA-Bw6, and HLA-DR fields will also be required for pancreas islet registrations. These data are being collected to improve the efficiency and safety of the allocation system by enhancing donor screening and to ensure that institutional members are complying with HLA typing policy. This proposal will result in adding optional fields for unacceptable DQA and DPB on the Waitlist.

Expected Implementation Plan:

If approved, the proposal will be effective pending programming in UNet℠ and notice to the OPTN membership.

Communication and Education Plan:

This proposal includes new policy requirements and new programmed fields impacting Waitlist and DonorNet®. Information about these new requirements may be included in an ongoing effort to provide instructional programs to members. The revised policy also would be incorporated into the OPTN Evaluation Plan, and instruction would possibly accompany ongoing efforts to notify members of periodic updates to the plan.

In addition, notification would be included in the following routine communication vehicles:

- Policy notice
- System notice
- UNOS Update article
- Member e-newsletter/member communications archive article
- Notification to a listserve group for target audiences

Compliance Monitoring:

Members will be expected to accurately report data based upon the proposed language. However, the proposed language will not change the current routine monitoring of OPTN members. Any data entered in UNet℠ may be subject to OPTN review, and members are required to provide documentation as requested.

Policy or Bylaw Proposal:

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~).

At a meeting of the OPTN/UNOS Board of Directors convened on November 12-13, 2014 in Richmond, Virginia, the following resolution is offered.

A resolution to approve expanding candidate and deceased donor HLA typing requirements to provide greater consistency across organ types.

Sponsoring Committee: Histocompatibility Committee

RESOLVED, that Policies 2.11.A (Required information for Deceased Kidney Donors); 2.11.B (Required information for Deceased Liver Donors); 2.11.C (Required Information for Deceased Heart Donors); 2.11.D (Required Information for Deceased Lung Donors); 2.11.E (Required Information for Deceased Pancreas Donors); 3.4.D (Candidate Human Leukocyte Antigen (HLA Information); and 4.2 (Requirements for Performing and Reporting HLA Typing); are modified or added as set forth below, effective pending programming and notice to membership.

2.11.A Required Information for Deceased Kidney Donors

The host OPO must provide *all* the following additional information for all deceased donor kidney offers:

1. Date of admission for the current hospitalization
2. Donor name
3. Donor ID
4. Ethnicity
5. Relevant past medical or social history
6. Current history of abdominal injuries and operations
7. Current history of average blood pressure, hypotensive episodes, average urine output, and oliguria
8. Current medication and transfusion history
9. Anatomical description, including number of blood vessels, ureters, and approximate length of each
10. Human leukocyte antigen (HLA) information as follows: A, B, Bw4, Bw6, C, DR51, DR52, DR53, DQA, ~~and~~ DQB, and DPB antigens prior to organ offers. ~~The lab is encouraged to report splits for all loci as outlined in *Policy 4: Histocompatibility*~~.
11. Indications of sepsis
12. Injuries to or abnormalities of the blood
13. Assurance that final blood and urine cultures are pending
14. Final urinalysis
15. Final blood urea nitrogen (BUN) and creatinine
16. Recovery blood pressure and urine output information
17. Recovery medications
18. Type of recovery procedure, flush solution and method, and flush storage solution
19. Warm ischemia time and organ flush characteristics

2.11.B Required Information for Deceased Liver Donors

The host OPO must provide *all* the following additional information for all deceased donor liver offers:

1. Donor name
2. Donor ID

3. Ethnicity
4. Height
5. Weight
6. Vital signs, including blood pressure, heart rate and temperature
7. Social history, including drug use
8. History of treatment in hospital including current medications, vasopressors, and hydration
9. Current history of hypotensive episodes, urine output, and oliguria
10. Indications of sepsis
11. Aspartate aminotransferase (AST)
12. Bilirubin (direct)
13. Other laboratory tests within the past 12 hours including:
    a. Alanine aminotransferase (ALT)
    b. Alkaline phosphatase
    c. Total bilirubin
    d. Creatinine
    e. Hemoglobin (hgb) and hemocrit (hct)
    f. International normalized ration (INR) or Prothrombin (PT) if INR is not available, and partial thromboplastin time (PTT)
    g. White blood cell count (WBC)
14. Human leukocyte antigen (HLA) typing if requested by the transplant hospital, including A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, DQA,DQB, and DPB antigens in the timeframe specified by the transplant program

If a transplant program requests HLA typing for a deceased liver donor, it must communicate this request to the OPO and the OPO must provide the HLA information listed above. The transplant program must document requests for donor HLA typing, including the turnaround time specified for reporting the donor HLA typing results. The OPO must document HLA typing provided to the requesting transplant program.

2.11.C Required Information for Deceased Heart Donors

The host OPO must provide *all* the following additional information for all deceased donor heart offers:

1. Height
2. Weight
3. Vital signs, including blood pressure, heart rate, and temperature
4. History of treatment in hospital including vasopressors and hydration
5. Cardiopulmonary, social, and drug activity histories
6. Details of any documented cardiac arrest or hypotensive episodes
7. 12-lead interpreted electrocardiogram
8. Arterial blood gas results and ventilator settings
9. Cardiology consult or echocardiogram, if the hospital has the facilities
10. Human leukocyte antigen (HLA) typing if requested by the transplant hospital, including A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, DQA, ~~and~~ DQB, and DPB antigens prior to final organ acceptance
11. Toxoplasma antibody (Ab) test result or an appropriate donor sample sent with the heart for testing at the transplant hospital

For heart deceased donors, if a transplant ~~hospital~~ program requires donor HLA typing prior to submitting a final organ acceptance, it must communicate this request to the OPO and document the request. The OPO must provide the HLA information ~~required in the~~ listed above and document that the information was provided to the transplant program. ~~The transplant hospital may request HLA-DPB typing, but the OPO need only provide it if its affiliated laboratory performs related testing.~~

The heart recovery team must have the opportunity to speak directly with the responsible ICU personnel or the onsite donor coordinator in order to obtain current information about the deceased donor's physiology.

2.11.D Required Information for Deceased Lung Donors

The host OPO must provide *all* the following additional information for all deceased lung donor offers:

1. Height
2. Weight
3. Vital signs, including blood pressure, heart rate, and temperature
4. History of medical treatment in hospital including vasopressors and hydration
5. Smoking history
6. Cardiopulmonary, social, and drug activity histories
7. Arterial blood gases and ventilator settings on 5 cm/H20/PEEP including PO2/FiO2 ratio and preferably 100% FiO2, within 2 hours prior to the offer
8. Bronchoscopy results
9. Chest x-ray interpreted by a radiologist or qualified physician within 3 hours prior to the offer
10. Details of any documented cardiac arrest or hypotensive episodes
11. Sputum gram stain, with description of sputum
12. Electrocardiogram
13. Echocardiogram, if the OPO has the facilities
14. HLA typing if requested by the transplant hospital, including A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, ~~and~~ DQA, DQB, and DPB antigens prior to final organ acceptance

If the host OPO cannot perform a bronchoscopy, it must document that it is unable to provide bronchoscopy results and the receiving transplant hospital may perform it. The lung recovery team may perform a confirmatory bronchoscopy provided unreasonable delays are avoided and deceased donor stability and the time limitations in *Policy 5.5.B: Time Limit for Acceptance* are maintained.

For lung deceased donors, if a transplant ~~hospital~~ program requires donor HLA typing prior to submitting a final organ acceptance, it must communicate this request to the OPO and document the request. The OPO must provide the HLA information ~~required in the~~ listed above and document that the information was provided to the transplant program. ~~The transplant hospital may request HLA-DPB typing, but the OPO need only provide it if its affiliated laboratory performs related testing.~~

The lung recovery team must have the opportunity to speak directly with the responsible ICU personnel or the onsite OPO donor coordinator in order to obtain current information about the deceased donor's physiology.

2.11.E Required Information for Deceased Pancreas Donors

The host OPO must provide *all* the following additional information for all deceased donor pancreas offers:

1. Donor name
2. Donor ID
3. Ethnicity
4. Weight
5. Date of admission for the current hospitalization
6. Alcohol use (if known)
7. Current history of abdominal injuries and operations including pancreatic trauma
8. Current history of average blood pressure, hypotensive episodes, cardiac arrest, average urine output, and oliguria

9. Current medication and transfusion history
10. Pertinent past medical or social history including pancreatitis
11. Familial history of diabetes
12. Insulin protocol
13. Indications of sepsis
14. Serum amylase
15. HLA information as follows: A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, ~~and~~ DQA, DQB, and DPB antigens prior to organ offers ~~The lab is encouraged to report splits for all loci as outlined in *Policy 4: Histocompatibility*.~~

3.4.D Candidate Human Leukocyte Antigen (HLA) Requirements

The candidate's transplant program must report to the OPTN Contractor complete human leukocyte antigen (HLA) information (at least 1A, 1B, and 1DR antigen) according to *Table 3-1* below:

Table 3-1: HLA Requirements

If the candidate is registered for a…	Then, HLA information is…
Kidney alone	Required
Kidney–pancreas	Required
Kidney with any other non-renal organ	Not required
Pancreas alone	Required
Pancreas islet alone	Required

Transplant programs must report this HLA information using current World Health Organization (WHO) nomenclature when the candidate is registered on the waiting list.

Policy 4: Histocompatibility

4.2 Requirements for Performing and Reporting HLA Typing

Laboratories must ensure that all HLA typing is accurately determined and report HLA typing results to the OPO or Transplant Program according to the turnaround time specified in the written agreement between the laboratory and any affiliated OPO or transplant program.

4.2.A Deceased Donor HLA Typing

If the laboratory performs HLA typing on a deceased donor, the laboratory must perform molecular typing and report results at the level of serological splits to the OPO for all required HLA types on deceased donors according to Table 4-3 Deceased Donor HLA Typing Requirements.

Table 4-3 below provides the requirements of HLA typing of HLA A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, DQA, DQB, and DPB antigens.

Table 4-3: Deceased Donor HLA Typing Requirements

If a Laboratory Performs HLA Typing on a:	Then the Laboratory Must Report Results to the OPO at the Following Times:
Deceased Kidney, Kidney-Pancreas, or Pancreas Donor	Prior to organ offers
Deceased Heart, Heart-Lung, or Lung Donors	Prior to final acceptance, if required by the transplant program
Deceased Liver Donors	Within the period specified by the transplant program

4.2.B HLA Typing for Candidates

Laboratories must perform HLA typing on a kidney, kidney-pancreas, or pancreas islet candidate and report results for HLA A, B, Bw4, Bw6, and DR to the transplant program prior to registration on the waiting list.

4.2~~2~~3 Resolving Discrepant Donor and Recipient HLA Typing Results

[*Subsequent headings affected by the re-numbering of this policy will also be changed as necessary*.]

#

Public Comment Responses

1. Public Comment Distribution

Date of distribution: March 14, 2014
Public comment end date: June 13, 2014

Public Comment Response Tally					
Type of Response	**Response Total**	**In Favor**	**In Favor as Amended**	**Opposed**	**No Vote/ No Comment/ Did Not Consider**
Individual	41	38 (92.68%)	N/A	0 (%)	3 (7.32%) no opinion
Regional	11	10 (%)	1 (9%)	0 (%)	0
Committee	19	5 (26.31%)	N/A	0 (%)	14 (73.68%)

2. Primary Public Comment Concerns/Questions

The Committee requested feedback during public comment on the following questions regarding HLA-DQA and HLA-DPB:

- Does your transplant program screen candidates for antibodies to HLA-DQA and HLA-DPB?
- If so, is it sufficient to have this donor HLA information recorded in DonorNet to use when making donor acceptance decisions? Or, is it imperative to add unacceptable antigen fields for these loci and program the UNOS system to automatically avoid those donors when unacceptable antigens are listed?

Many commenters stated that histocompatibility laboratories already screen candidates for antibodies to HLA-DQA and HLA-DPB or have the capacity to perform the screening. Public comment feedback revealed that commenters are in agreement that HLA-DQA and HLA-DPB should be required to be reported for deceased donors. To that point, there is also consensus around the community that HLA-DQA and HLA-DPB fields should be programmed in DonorNet® to use in making donor acceptance decisions and in Waitlist as unacceptable antigens for automatic avoidance.

Several commenters requested the inclusion of DPA to the list of loci required for deceased donors and suggested using internationally recognized standard nomenclature and ensure that all recognized HLA antigens are listed.

3. Regional Public Comment Responses

Region	Meeting Date	Motion to Approve as Written	Approved as Amended (see below)	Meeting Format
1	5/5/2014	10 yes, 0 no, 1 abstention		In person
2	03/28/2014	22 yes, 4 no, 0 abstentions		In person
3	5/30/2014	17 yes, 0 no, 0 abstentions		In person
4	5/9/2014	11 yes, 11 no, 0 abstentions	22 yes, 0 no, 0 abstentions	In person
5	6/12/2014	26 yes, 1 no, 0 abstentions		In person
6	5/16/2014	55 yes, 0 no, 1 abstention		In person
7	5/9/2014	21 yes, 0 no, 0 abstentions		In person
8	4/4/2014	17 yes, 0 no, 1 abstention		In person
9	5/21/2014	14 yes, 0 no, 2 abstentions		In person
10	5/15/2014	18 yes, 0 no, 2 abstentions		In person
11	5/30/2014	24 yes, 0 no, 0 abstentions		In person

Region 4 approved an amendment to add DPA to the list of HLA loci required to be reported for deceased donors.

4. Committee Public Comment Responses

The Kidney Transplantation Committee strongly favors this proposal and for programming unacceptable antigen fields in Unet^{SM}. The Kidney Transplantation Committee argued that only programming HLA-DQA and HLA-DPB in DonorNet® creates a patient safety risk and is burdensome to the transplant team when making "middle of the night" acceptance decisions. The Kidney Transplantation Committee also believes the addition will be crucial with implementation of broader sharing for highly sensitized candidates in new KAS.

The Pancreas Transplantation Committee agrees with this proposal and for programming unacceptable antigen fields in UNet^{SM}. Furthermore, the Pancreas Transplantation Committee maintains that only programming these fields into DonorNet® creates a patient safety risk.

The Operations and Safety Committee considered this proposal during its June 2014 teleconference meeting and voted in support of the proposal and of programming unacceptable antigen fields in UNet^{SM}.

5. Individual Public Comment Responses

Four professional societies provided feedback during public comment: ASHI, CAP, ASTS, and AST. All four societies are in agreement that HLA-DQA and HLA-DPB fields should be added to DonorNet® to use in making donor acceptance decisions and in Waitlist[SM] as unacceptable antigens for automatic avoidance. An overwhelming majority of commenters, including the professional societies, requested that UNet[SM] be programmed to automatically avoid donors when unacceptable antigens are listed rather than trying to make a decision in the middle of the night when the organ is initially offered.

Post Public Comment Consideration:

The Committee met in person on August 11-12, 2014 to review public comments received on this proposal. During review of the public comments, members agreed that HLA-DPA should be included in the list of loci, however, this change was considered outside the scope of this proposal and would need to be addressed through the development of a new project.

As a result of favorable public comment, the Committee voted unanimously to recommend approval of the proposal, without changes, to the Board of Directors. In response to specific public comment feedback on whether to include HLA-DQA and HLA-DPB fields in DonorNet® only or to DonorNet® and Waitlist[SM], the Committee unanimously agreed with the majority of commenters that the proposal should be programmed to include HLA-DQA and HLA-DPB fields in DonorNet® and HLA-DQA and HLA-DPB fields in Waitlist[SM] as unacceptable antigens.